



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/825,769	04/04/2001	Milan S. Blake	NV1932	3657

7590 07/28/2003

Baxter Healthcare Corporation
P.O. Box 15210
Irvine, CA 92614

EXAMINER

FORD, VANESSA L

ART UNIT	PAPER NUMBER
----------	--------------

1645

DATE MAILED: 07/28/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

09/825,769

Applicant(s)

BLAKE ET AL.

Examiner

Vanessa L. Ford

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondenc address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 May 2003 .
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 1 and 4-9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,3 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 April 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 .
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. Applicant's response to the Restriction requirement and election of Group II, claims 2, with traverse filed on September 26, 2002 is acknowledged. Applicant's preliminary amendment filed September 26, 2002 is acknowledged. Claims 9 and 10 have been added. Newly presented claim 9 is grouped with the invention of Group I and newly presented claim 10 is grouped with the invention in Group II. Therefore, claims 1 and 4-9 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being to a non-elected invention.

Applicant's traverse was on the grounds that Group I and Group II should be rejoined and examined together since Groups I and II form one inventive concept.

These arguments have been fully considered but are not found to be persuasive for the reasons below:

First, the classification system has no statutory recognition whether inventions are independent and distinct. For example, each class and subclass is comprised of numerous completely independent and distinct patented inventions.

Second, MPEP 803 states that restriction is proper between patentably distinct inventions where the inventions are (1) independent or distinct as claimed and (2) a serious search and examination burden is placed on the examiner if restriction is not required.

The term "distinct" is defined to mean that two or more subjects as disclosed are related, for example as product and method of use, etc., but are capable of separate manufacture, use or sale as claimed, and are patentable over each (see MPEP 802.01).

Art Unit: 1645

In the instant situation, the inventions of Groups I-II are drawn to distinct inventions which are a product and a method which are capable of separate manufacture, use or sale as described in the previous Office Action.

Classification of the subject matter is merely one indication of the burdensome nature of the search. The literature search, particularly relevant in this art, is not co-extensive, because for example, Group I is drawn to a product (i.e. *B. pertussis* cysteine desulfonase knockout mutant). Groups II is a drawn to method which require different method steps, parameters and endpoints (i.e. a method of producing pertussis toxin) . The mutant of Group I can be used in a materially different purposes such as a method of producing recombinant proteins. Clearly different searches and issues are involved in the examination of each Group. Therefore Group I and Group II are independent and distinct inventions. However, upon reconsideration, Group III, claim 3 which is drawn to a method of enhanced production of PT comprising cultivating *B. pertussis* cysteine desulfonase knockout mutant has been rejoined with the elected invention and will be examined. Claims 2-3 and 10 are under examination.

Specification

2. The specification is objected to because of the following informalities: *Bordetella pertussis* is the name of a genus and species of a microorganism. The names of genus and species should be italicized or underlined. For example, see page 1. Applicant is asked to review the specification for these types of informalities and correction is required.

Art Unit: 1645

3. The specification is objected to because of the use of worldwide web addresses on page 1. The worldwide web address can be readily changed and therefore, may not be available to the public. The specification should be reviewed for worldwide web addresses and the web address must be deleted from the specification.

Claim Objections

4. Claim 2 recites "*B. pertussis*" which should be underlined or italicized.

5. Claims 2 and 3 recite "PT" which should be changed to "Pertussis toxin". The proper name should be used in the claims.

6. Claims 2 and 3 recite "*B. pertussis*" which should be changed to "*Bordetella pertussis*". The proper name should be used at first occurrence in the claims.

Drawings

7. The drawings are objected to by the Draftsman under 37 CFR 1.84 or 1.152. See the attached form PTO 948.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 2-3 and 10 are rejected under 35 U.S.C. 112, first paragraph as containing subject matter which lacks written description in the specification in such a way as to enable one skilled in the art to which it pertains or with which it is most nearly connected to make and/or use the invention.

The claims are drawn to a method for producing PT comprising a *B. pertussis* cysteine desulfinate knockout mutant in a *B. pertussis* culture medium and isolating the PT from the culture medium and a method of enhanced production of PT comprising cultivating *B. pertussis* cysteine desulfinate knockout mutant.

The claims broadly encompass a genus of cysteine desulfinate genes. There is substantial variability among the species of cysteine desulfinate genes encompassed within the scope of the claims. The specification does not place any structure limitations on the cysteine desulfinate gene. The scope of the claims include numerous structural variants and the genus is highly variant because a significant number of structural difference between genus members is permitted. Structural features that could distinguish compounds in the genus from others in the gene class are missing from the disclosure and the claims. No common structural attributes identify

Art Unit: 1645

the members of the genus. Since there is no structure in the claim to define the cysteine desulfinate gene, the claimed genus includes cysteine desulfinate genes produced by other microorganisms. For Example, Mihara et al, (*The Journal of Biological Chemistry*, Vol. 272, No. 36, p. 22417-22424) teach that *Escherichia coli* appears to contain three nifS-like genes which encode NIFS-like protein (page 22417). Mihara et al teach that the NIFS-like proteins encoded by the nifS gene of *E. coli* has cysteine desulfurase activities. Mihara et al teach that nifS and NIFS-like proteins are found in a number of microorganisms (see Table III). Since the claimed genus encompasses genes of other microorganisms and genes yet to be discovered, the mere recitation of a "cysteine desulfinate knockout mutant" does not provide an adequate written description of the claimed genus since no structure accompanies the function of cysteine desulfurase activity. One skilled in the art would not recognize from the claimed disclosure that the applicant was in possession of the genus of nucleic acid sequences that are required to use the claimed method of producing PT comprising a *B. pertussis* cysteine desulfinate knockout mutant in a *B. pertussis* culture medium and isolating the PT from the culture medium. The recitation of "cysteine desulfinate knockout mutant" does not convey a common structure. As such, generic nucleic acid sequences that are unrelated via structure are highly variant and not conveyed by way of the written description in the specification at the time of filing. Therefore, the specification lacks written description for the highly variant genus of nucleic acid sequences that have cysteine desulfinate activity and one of skill in the would not

recognize that Applicants had possession of the genus of the claimed genes for use in the method as instantly claimed method.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 3 is rejected under 35 USC 112 second paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites “whereby an enhanced amount of PT produced is produced compared”. It is unclear as to what the applicant is referring? Correction is required.

10. Claim 3 is rejected under 35 USC 112 second paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites “non-cysteine desulfinate knockout mutant”. It is unclear as to what the applicant is referring? Correction is required.

11. Claim 10 is rejected under 35 USC 112 second paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recites “wherein the *B. pertussis* cysteine desulfinate is identified by knockout mutant ATCC Accession number PTA-3254”. There is no “B.

Art Unit: 1645

pertussis cysteine desulfurase" in claim 2 and is the accession number "knockout mutant ATCC Accession number PTA-3254". It is unclear as to what the applicant is referring? Correction is required.

Status of Claims


12. No claims allowed.

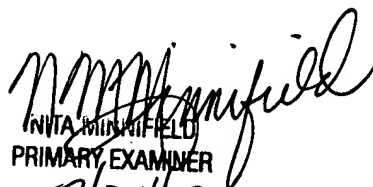
Conclusion

13. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 308-4242.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (703) 308-4735. The examiner can normally be reached on Monday – Friday from 7:30 AM to 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909.


Vanessa L. Ford
Biotechnology Patent Examiner
July 22, 2003


NITA MINNIFIELD
PRIMARY EXAMINER
7/24/03